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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/509,934	05/03/2000	ANDREAS STEINMEYER	SCH1747	6707

7590 03/28/2005

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EXAMINER

QAZI, SABIHA NAIM

ART UNIT

PAPER NUMBER

1616

DATE MAILED: 03/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/509,934

Applicant(s)

STEINMEYER ET AL.

Examiner

Sabiha Qazi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 December 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☒ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 5, 6, 8-11 and 14-50 is/are pending in the application.
- 4a) Of the above claim(s) 8-11 entirely; 1-3, 5, 6, 14, 20-50 (in part) is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☒ Claim(s) 1-3, 5, 6, 14, 20-50 (in part) is/are objected to.
- 8) ☒ Claim(s) 8-11 entirely; 1-3, 5, 6, 14, 20-50 (in part) are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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Non-Final Office Action

Claims 1-3,5,6,8-11 and 14-50 are pending. Acknowledgment is made of the response filed on December 9, 2004.

Allowable Subject Matter

Claims 1-3, 5, 6, 14, 20-50 (in part), drawn to compounds, compositions and their process of making when R1 and R2 is methylene, V and W together present a double bond, R3 and R4 represent a H or an alkyl group are objected to for containing non-elected subject matter.

The closest prior art is KIRSCH et al (US 6376480 B1). The Applicants have disclaimed the compounds of this reference.

Response to Arguments

Examiner's Notes

Amendments have been entered.

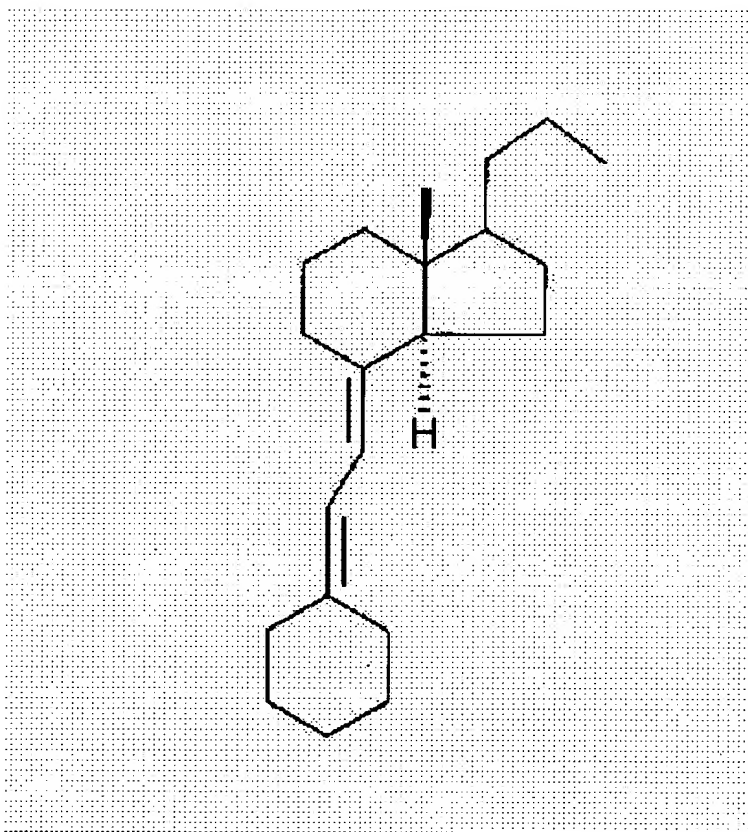
Claim 6 does not define method steps. If Applicants want to include this process of making claim, the steps must be clearly defined. How are the various steps performed and the specific reagents used.

Election

The Applicants argue, "These are common alternative groups for this position in compounds within the class of Vitamin D derivatives, well recognized within the art. See, e.g.,

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US 6,630,031, US 6,153,605, US 5,929,056, all of which are of record. Such well recognized alternative groups within the art demonstrate that a Restriction between such groups is unwarranted, especially since such a large relative portion of the structure of the compounds remains unchanged. Therefore, restriction between these groups should be withdrawn.”



The Examiner respectfully disagrees, as the indicated structure does not imply any common feature that would distinguish the claimed subject matter from that known in the prior art. The Applicants are requested to see page 222 of BOUILLON et al¹, which teaches the addition of a keto group restores the cell-differentiating activity and reduces the calcemic activity 3 times. The paragraph that starts with, “1. Addition or transposition of hydroxyl groups”

¹ Journal Entry: BOUILLON et al, Structure-Function Relationships in the Vitamin D Endocrine System, *Endocrine Reviews*, Vol. 16, No. 2, pp 200-257, 1995. See the entire document.

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where the influence on cell differentiation and calcemic activity that occurs as a consequence of an addition of a second hydroxy group at carbon 22, 23, 24, or 26 of 1 α ,25-dihydroxy vitamin D₃ has been shown. The reference teaches, "Moving the hydroxy group to carbon 22 or 23 in combination with a shorter side chain reduces the cell-differentiating activity 200 times." It is clear that even the change of one position in a hydroxy group changes the effect.

Similarly, the Applicant the paragraph starting with "*2. Introduction of unsaturation*" It is known that birds discriminate vitamin D₂ compounds whereas mammals do not. This paragraph teaches the importance of the double bond in vitamin D.

It will be a burden on the Examiner to search such a large variety of compounds thoroughly.

The Applicant is requested to amend the claims to the elected group.

The Applicants are claiming at 2-substituted vitamin D compounds as well as 19-nor compounds. The Examiner would like to refer the Applicants to DELUCA et al²'s abstract, where it states, "This invention provides a novel class of vitamin D related compounds, namely, the 2-alkyl-19-nor-vitamin D derivatives, as well as a general method for their chemical synthesis. These 2-substituted compounds, especially the 2. α -methyl and the 2. α -methyl-20S derivatives, are characterized by relatively low intestinal calcium transport activity and high bone calcium mobilization activity resulting in novel therapeutic agents for the treatment of diseases where bone formation is desired, particularly low bone turnover osteoporosis."

² United States Patent No. 6,127,559. See the entire document, especially the abstract.

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It is clear that even the *slightest* change in the structure affects the biological activity in vitamin D compounds. The Applicants are claiming such a broad genus having 2-substituted compounds, 19-nor compounds, and various substituents at 20 position. Furthermore, Z may be carbocyclic, heterocyclic, or non-heterocyclic. These are not all obvious alternatives, as has been argued by the Applicants. The structure drawn (above) does not contribute any specific utility.

This application is in condition for allowance except for the following formal matters:

Claims 1-3, 5, 6, 14, 20-50 (in part), drawn to compounds, compositions and their process of making when R1 and R2 is methylene, V and W together present a double bond, R3 and R4 represent a H or an alkyl group are objected to for containing non-elected subject matter.

The closest prior art is KIRSCH et al (US 6376480 B1). The Applicants have disclaimed the compounds of this reference.

The Applicants must cancel non-elected invention while responding to this action.

Prosecution on the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

A shortened statutory period for reply to this action is set to expire **TWO MONTHS** from the mailing date of this letter.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sabiha Qazi whose telephone number is (571) 272-0622. The examiner can normally be reached on any business day.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (571) 272-0887. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



SABIHA QAZI, PH.D
PRIMARY EXAMINER

Sunday, March 20, 2005